Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

MDL No.: 2327

THIS DOCUMENT RELATES TO:
ROSE MARIE BUSHWAY, et al.
Civil Action No.: 2:16-cv-08070

RULE 26 CASE SPECIFIC EXPERT REPORT OF KONSTANTIN WALMSLEY, M.D.

I am Dr. Konstantin Walmsley. Any medical opinions rendered in this report represent my opinions, all held to a reasonable degree of medical certainty, and are based on a reasonable medical probability and scientifically reliable evidence. All opinions are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature.

I. QUALIFICATIONS

I am a licensed physician in the State of New Jersey and a board-certified urologist. I am familiar with the evaluation and treatment of pelvic organ prolapse and stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices. Specifically, I am familiar with Ethicon, Inc.'s ("Ethicon") products, including but not limited to the Prolift and TVT-O products. I have implanted these devices in my patients. I have attended training provided by mesh manufacturers, including Ethicon, regarding these devices. I have reviewed the IFU's for the Ethicon products and reviewed the independent medical literature. Additionally, I have explanted and performed other revision procedures on SUI and POP kits.

In light of my training, knowledge, experience, and qualifications set forth above and in the attached CV, I am familiar with the standards of care applicable in the jurisdiction where the Plaintiff resides as to surgical technique for implantation of the below-referenced Ethicon devices.

Additionally, because of my training, knowledge, experience, and qualifications as set forth above and in the attached CV, I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants. The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, incomplete emptying, and urinary retention), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients' complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

A copy of my CV is attached as Exhibit "A", and a copy of my testimony for the last four years and Fee Schedule is attached as Exhibit "B". The documents I relied upon for this report are contained in Exhibit "C" as well as those documents cited throughout this report.

II. SUMMARY OF CASE SPECIFIC OPINIONS

In formulating my opinions and preparing this report, I reviewed scientific literature, corporate documents from Ethicon, Inc., ("Ethicon"), sample products and depositions

of Ethicon employees and witnesses. The corporate documents, sample products, and depositions were supplied to me by counsel. A list of general materials relied upon and incorporated herein by reference is found within my General Report for these products. Other materials relied upon for this report are listed in Exhibit "C." I have also relied on general causation reports for other Ethicon products. I have reviewed all available medical records in this case. All opinions I have are to a reasonable degree of medical and scientific certainty. I understand that discovery is still ongoing in this case, and I reserve my right to amend my opinions if further information is provided in any form including, but not limited to, corporate documents, depositions, and the expert reports of both Plaintiff and Defense experts. In formulating my opinions herein, I also relied upon my clinical experience in treating stress urinary incontinence.

It is my opinion, to a reasonable degree of medical and scientific certainty, that debilitating injuries Mrs. Bushway suffered, some of which are discussed below, and the majority of her post-implant medical course are a direct result of implanting the Ethicon TVT-Obturator and Prolift mesh devices. As discussed in my general liability reports, the mesh products are not suitable for their intended application as a permanent prosthetic implants for the treatment of pelvic organ prolapse and stress urinary incontinence because of the following characteristics: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh that was never intended to be implanted inside the pelvic cavity and is incompatible with the naturally occurring conditions of the vagina including peroxides and bacteria; (d) deformation, rigidity, fraying, roping, cording, and curling of the mesh; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; and (h) the difficulty and/or impossibility of removing the devices.

As a result, these mesh devices are not suitable for their intended applications as permanent prosthetic implants for pelvic floor repair in women, such as Mrs. Bushway. Ethicon failed to act as reasonable and prudent medical device manufacturer by manufacturing and selling its polypropylene mesh in permanent implants like their TVT-Obturator and Prolift devices. As a result of these and other inadequacies, it is my opinion to a reasonable degree of medical certainty that the implantation of these devices caused Mrs. Bushway to suffer injuries which are permanent in nature. These injuries include: continued and worsening urinary incontinence, urinary frequency, urgency, nocturia, vaginal and pelvic pain, urinary tract infections, inflammation, scar formation, and the need for Interstim implantation due to voiding dysfunction.

The medical treatment required to treat Mrs. Bushway's injuries caused by the mesh products was a foreseeable result of her complications. In formulating my opinions and preparing this report, I considered the scientific literature, corporate documents from Ethicon, and case-specific materials such as medical records and deposition testimony. I further considered my own clinical experience in treating stress urinary incontinence and pelvic organ prolapse in my practice. The corporate documents were provided to me by counsel. I have also relied upon the Ethicon TVT-Obturator General Causation report authored by Dr. Bruce Rosenzweig, the Prolift General Causation Report authored by Dr. Abbas Shobeiri, and the Gynecare Prolift General Causation Report authored by Dr. Donald Ostergard in the MDL. All opinions I have offered are held to a reasonable degree of medical and scientific certainty.

III. CASE SUMMARY

Throughout my analysis of Mrs. Bushway's conditions, I have relied upon her medical records and medical history to date. Her medical history is outlined as follows:

At the time of implant, Mrs. Bushway was a 68- year-old gravida 4, para 4 patient. Her four births were vaginal deliveries. Her past medical history was remarkable for stress urinary incontinence, rectocele, cystocele, right inguinal hernia, left inguinal hernia, left kidney cyst, small hiatal hernia, asthma, diabetes, and hyperlipidemia. Her past surgical history was remarkable for hysterectomy, left hip replacement, right hip replacement, posterior colporrhaphy with insertion of Prolift mesh, vaginal vault suspension with sacrospinous fixation, TVT-O and cystoscopy. She was a former smoker of approximately 25 years.

On October 23, 2008, Mrs. Bushway was implanted with an Ethicon Prolift for a rectocele and an Ethicon TVT-Obturator for incontinence. The surgical procedure also included a sacrospinous fixation and cystoscopy. Dr. Paige Gernt performed the surgery at Cookeville Regional Medical Center. At the time of implant, her preoperative and postoperative diagnosis included the following: rectocele, cystocele, vaginal prolapse, and incontinence. The procedure performed included a posterior colporrhaphy with insertion of Prolift mesh, vaginal vault suspension with sacrospinous fixation, TVT-O and cystoscopy. During the cystoscopy, a small blood clot was identified in the bladder. Dr. Lee Moore, urologist, was consulted intraoperatively. Dr. Moore also performed a cystoscopy and agreed there was no defect. The clot was attached to the bladder neck at about the three or four o'clock position. Dr. Moore used the graspers and pulled the clot off resulting in a small amount of bleeding that quickly resolved. No abnormalities were noted.

On March 15, 2016, Mrs. Bushway was seen by Dr. Bert Geer at Cook Regional Medical Center. Mrs. Bushway reported incontinence, urgency, frequency and nocturia. She was diagnosed with a cystocele and rectocele. Mrs. Bushway also had a UTI and was prescribed Macrobid. She was scheduled for multichannel urodynamics.

On March 17, 2016, the results of a urinalysis collected on March 15 were positive for nitrites and Escherichia coli.

On March 25, 2016, Urodynamics performed at Cookeville Gynecology by Dr. Bert Geer showed PVR 80cc, detrusor instability, and urge incontinence. Mrs. Bushway' s results also indicated atrophic vaginitis, increased frequency, nocturia, and atrophy of the skeletal muscle of the pelvis. Mrs. Bushway was prescribed Vesicare and referred for pelvic floor therapy. An overactive bladder plan was discussed medical in combination with behavioral therapy was initiated.

On April 13. 2016, Mrs. Bushway called Cookeville Gynecology to report the Vesicare was improving her OAB symptoms. Mrs. Bushway reported she had been doing PT exercises but was currently in Florida, so she had not been going to PT. Mrs. Bushway was prescribed Vesicare.

On June 14, 2016, Mrs. Bushway called Cookeville Gynecology to report she could not afford Vesicare. She had switched back to Oxybutynin and was doing pelvic floor therapy. Her OAB symptoms had improved somewhat.

On June 21, 2016, Mrs. Bushway called Cookeville Gynecology to report she was doing well with pelvic floor therapy and Oxybutynin. Her OAB symptoms were better. She canceled her appointment on June 28. She was to receive a follow-up phone call in 6 weeks after completing pelvic floor therapy.

On July 13, 2016, Mrs. Bushway was discharged from physical therapy. Her discharge information noted she has been having increased difficulty with weakness and a decline in mobility with increased stress incontinence.

On August 18, 2016, Mrs. Bushway called Cookeville Gynecology and stated she was currently on Oxybutynin due to cost of Vesicare. Mrs. Bushway stated she was experiencing some signs and symptoms of relief. Mrs. Bushway also mentioned she had been doing pelvic floor exercises but had not noticed any changes.

On January 30, 2017, Mrs. Bushway visited Dr. Bert Geer at Cookeville Gynecology with complaints of urge incontinence, nocturia, and increased frequency of urination. Dr. Geer planned for InterStim peripheral nerve evaluation.

On February 27, 2017, Mrs. Bushway visited Cookeville Gynecology and reported urge incontinence, nocturia, increased frequency, changing 2-3 pads per day. She had tried Oxybutynin, Vesicare, Kegel exercise and pelvic floor therapy.

On February 28, 2017, Mrs. Bushway visited Cookeville Gynecology and reported urinary urgency, urge incontinence of urine, nocturia, increased frequency of urination; she was found via physical exam to have a grade I cystocele POP-Q -2, and a grade 1 rectocele POP-Q -3. Peripheral Nerve Evaluation was performed. Dr. Bert Geer subsequently suggested Mrs. Bushway would be a candidate for permanent Stage I and Stage II InterStim implantation.

On March 1, 2017, Mrs. Bushway saw Dr. Bert Geer for PNE lead removal. Dr. Geer removed the leads from S3 foramen.

On March 21, 2017, Mrs. Bushway saw Dr. Bert Greet and reported continued urinary urgency, incontinence, nocturia, and increased frequency of urination. Mrs. Bushway desired to proceed with Stage I InterStim.

On March 22, 2017, Mrs. Bushway underwent insertion of InterStim stage I lead for urge urinary incontinence and urinary frequency under local with IV sedation. The procedure was performed by Dr. Bert Geer at Cookeville Regional Medical Center.

On March 27, 2017, Mrs. Bushway saw Dr. Bert Geer for a follow-up post stage I InterStim placement. Mrs. Bushway reported she was improved and Dr. Geer scheduled her for InterStim Stage 2.

On March 29, 2017, Mrs. Bushway underwent insertion of InterStim stage II lead for urge urinary incontinence and urinary frequency under local with IV sedation. Dr. Bert Geer performed the procedure at Cookeville Regional Medical Center.

On April 18, 2017, Mrs. Bushway saw Dr. Bert Geer 3 weeks post op InterStim stage II. Dr. Geer noted Mrs. Bushway doing well and at this point she may resume routine normal activities as she feels like it.

On May 15, 2017, during telephone conversation between Mrs. Bushway and Lisa Geer, RN at Cookeville Gynecology, Mrs. Bushway reported that the InterStim not working.

On May 25, 2017, Mrs. Bushway called Cookeville Gynecology and reported that the InterStim does not seem to be helping with LUTS. Mrs. Bushway also noted she had increased stimulation and she felt stimulation in vagina.

IV. CASE SPECIFIC EXPERT OPINIONS

Mrs. Bushway was implanted with Ethicon's Prolift and TVT-Obturator devices on October 23, 2008, and both the TVT-Obturator and the Prolift significantly caused her injuries. Mrs. Bushway should not have been implanted with the Ethicon TVT-Obturator and the Prolift because the poor design of the devices increased the risk of serious complications and caused her

specific complications. These complications include but are not limited to: continued and worsening urinary incontinence, urinary frequency, urgency, nocturia, vaginal and pelvic pain, urinary tract infections, inflammation, scar formation, and the need for Interstim implantation.

In determining the cause of a specific injury, it is necessary to "rule in" potential causes of the injury and then, by process of elimination, "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis or differential etiology and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I have used that methodology in arriving at my opinions in this case. In general, my expert opinions can be summarized as follows:

A. Ethicon's construction mesh, used in the TVT-Obturator and Prolift devices, is not suitable for its intended application as permanent prosthetic implants for stress urinary incontinence because the pores are too small, it is a heavy weight mesh, it degrades over time, and it can cause chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, biofilm formation and infections; in addition, the mesh has sharp edges, and has been found to rope, curl, and deform. Under tension, the pores have been found to collapse.

B. Ethicon knew that its TVT-Obturator and Prolift mesh devices were not appropriate for use, but it failed to modify/change the mesh to a larger pore size or a lighter weight mesh that would be less likely to degrade, cause excessive foreign body reactions or chronic inflammation, or deform, become rigid, fray, rope, or cord after implantation, and cause the formation of fibrotic bridging that leads to scar plate formation and mesh encapsulation, which makes these devices difficult if not impossible to remove. According to Ethicon's internal

documents, it was unwilling to change the mesh because of its economic interest in maintaining its competitive advantage in the market and, therefore, Ethicon put profits before patient safety.

C. Ethicon's TVT-Obturator and Prolift devices have design flaws because they cannot adequately describe, inform, or explain to physicians how to properly "tension" the device. Further, the devices shrink, contract, rope, and curl making it difficult or impossible to tension in a safe manner for patients.

D. Ethicon's meshes are not suitable for permanent implant because the Material Safety Data Sheet ("MSDS") for the polypropylene resin used to manufacture Ethicon's polypropylene states that its polypropylene is incompatible with strong oxidizers such as peroxides which are readily found in the vagina.

E. Ethicon's mesh devices are also not suitable for permanent implant because the toxicity testing of the polypropylene mesh revealed that it was cytotoxic which can cause cell death and complications.

F. Ethicon's warnings and disclosures of adverse events in their Instructions for Use ("IFU") for these devices have been inadequate based on the adverse reactions and risks associated with them that have been known to Ethicon from the time these devices were first sold and marketed. Ethicon did not disclose information to physicians in their IFU regarding characteristics of their devices that makes them unsuitable for their intended application as a permanent prosthetic implant for pelvic floor repair. This includes - small pore size; heavy weight mesh; the mesh's tendency to degrade over time which causes chronic foreign body reactions, fibrotic bridging, contraction, shrinkage, fraying, loss of particles, roping, curling, or deform; the pores collapsing with tension; the mesh becoming difficult or impossible to remove;

the mesh testing positive for cytotoxicity; and, the MSDS stating that it is incompatible with strong oxidizers, such as peroxides.

G. The design of these devices is flawed because they are not designed for special patient populations, nor does the IFU nor marketing documents inform physicians that certain patients will have poorer outcomes and higher risks.

H. Ethicon failed to reveal material facts about complication and conflicts of interest regarding key studies in key marketing documents.

I. The benefits of these mesh products are outweighed by the severe, debilitating, and life changing complications associated with them and there were safer alternative options available.

J. As a result of the defects in these meshes, Mrs. Bushway suffered and continues to suffer life-long injuries.

Based on my background, education, training, and experience, as well as the medical records offered in this case, it is my opinion that Dr. Paige Gernt's treatment of Mrs. Bushway met the standard of care. The pre-operative evaluations of the patient met the standard of care. The TVT-Obturator and Prolift meshes were implanted due to complaints of symptomatic cystocele and rectocele, with stress urinary incontinence; and surgery was performed within the standard of care with no evidence of surgeon error or deviation from the manufacturer's procedural steps.

After implant of these meshes, Mrs. Bushway developed the following injuries: continued and worsening urinary incontinence, urinary frequency, urgency, nocturia, vaginal and pelvic pain, urinary tract infections, inflammation, scar formation, and the need for Interstim implantation. The small pore size, heavy weight mesh, degradation, chronic foreign body

response, fibrotic bridging, contracting and shrinking, fraying, particle loss, biofilm formation and infections, sharp edges, roping, curling and deformation, and the collapsing of pores within the Ethicon TVT-Obturator and Prolift meshes caused these symptoms. Furthermore, her symptoms of continued and worsening urinary incontinence, urinary frequency, urgency, nocturia, vaginal and pelvic pain, urinary tract infections, inflammation, scar formation, and voiding dysfunction requiring such procedures as Interstim implantation are consistent with known complications such as those described above and is associated with and caused by these mesh products. To a reasonable degree of medical certainty, the meshes implanted and their effects on the surrounding tissues are the causes of Mrs. Bushway's injuries. It is my opinion that both mesh products caused or contributed to the injuries Ms. Bushway suffered, which have been outlined in this report.

Mrs. Bushway's medical history is remarkable for continued and worsening urinary incontinence, urgency, infections, cystocele, rectocele, nocturia, vaginal and pelvic pain. Mrs. Bushway's conditions included**:** continued and worsening urinary incontinence, urinary frequency, urgency, nocturia, vaginal and pelvic pain, urinary tract infections, cystocele, rectocele, atrophy of skeletal muscle of pelvis, inflammation and scar formation, and Interstim implantation. The timing of the symptoms, the severity and continual nature of the symptoms, combined with the nature of her conditions provide the relevant information regarding the differential diagnosis.

I did consider her past medical history which included: she was a gravida 4, para 4 patient. All births were vaginal deliveries. Her past medical history was remarkable for asthma, diabetes, multiple hip replacements, pelvic organ prolapse and stress urinary incontinence. Her past surgical history was remarkable for hysterectomy, multiple hip replacements, posterior

colporrhaphy with insertion of Prolift mesh, vaginal vault suspension with sacrospinous fixation, TVT-O and cystoscopy. She is a former smoker of approximately 25 years. None of these conditions were factors in her current injuries.

To a reasonable degree of medical certainty, the small pore size, the heavy weight mesh, degradation over time, chronic foreign body reactions, fibrotic bridging, mesh contracture and shrinkage, fraying, particle loss, biofilm formation and infections, sharp edges, roping, curling and deformation, and the pore collapsing with tension of the meshes implanted caused Mrs. Bushway's symptomatology. It is my opinion that she will continue to suffer from long term risks of continued and worsening urinary incontinence, urgency, pelvic pain/trauma, chronic constipation, chronic urinary retention, infection, and vaginal pain. She will likely also continue to experience chronic foreign body reaction and chronic inflammation. As a result, Mrs. Bushway may need additional surgeries to remove remaining Ethicon meshes and treat vaginal scarring, pelvic pain, incontinence, and other injuries associated with the original implantation of the devices. She will have the possibility of future risks and symptoms as long as there is mesh material left in her body. Mrs. Bushway will likely require additional pelvic floor therapy and physical therapy to alleviate her symptoms which stem from the implant of these devices.

Based on my review of the entire body of literature, my experience, review of Mrs. Bushway's medical records and the deposition testimony provided to me by counsel, it is my opinion, to a reasonable degree of medical certainty, Mrs. Bushway would not have developed the aforementioned symptoms, or the need to undergo additional treatments to the extent that she has, had the Ethicon TVT-Obturator and Prolift meshes never been implanted.

It is my opinion that there were reasonably feasible alternatives available to Ethicon's mesh devices, and for the treatment of Mrs. Bushway. Even other lightweight meshes would have been a safer alternative to the Ethicon meshes implanted in Mrs. Bushway.

Safer alternative designs, rather than the Marlex polypropylene mesh products, existed for this patient. I have experience with many of these safer alternative designs; and, based on my experience and review of medical literature and other materials, it is my opinion that these alternative designs were safer and feasible for Mrs. Bushway. These safer alternative designs include:

(1) the use of sutures, including delayed absorbable sutures like PDS, in a native tissue POP repair or Burch colposuspension for SUI;

(2) autologous fascia sling;

(3) an allograft sling or POP repair with products such as certain biological graft materials; and

(4) a sling or POP repair with less polypropylene such as Ultrapro.

These safer alternative designs were capable of preventing Mrs. Bushway's injuries and damages, as I have described in my report, that were a result of the specific design flaws of the Ethicon TVT-Obturator and Prolift devices using Marlex polypropylene, including degradation, cytotoxicity, stiffness, migration, deformation, fraying, roping, cording, curling, banding, scarring, shrinkage/contraction, scar plate formation, chronic inflammation, chronic foreign body reaction, loss of pore size with tension, dense, heavy, and frayed, rough edges. If any of these safer alternative designs been used for Mrs. Bushway, she would not have suffered the injuries I

set forth in my report, as her injuries were caused by the specific design flaws of the Ethicon TVT-Obturator and Prolift devices discussed above and in my general reports. The likelihood that the Ethicon TVT-Obturator and Prolift designs would cause Mrs. Bushway's injuries and damages and the gravity of those injuries and damages outweighed the burden on Ethicon of adopting such alternative designs and the adverse effects, if any, of such alternative designs on the utility of the Ethicon TVT-Obturator and Prolift products. The inadequate warnings about the Ethicon TVT-Obturator and Prolift devices significantly increased the likelihood of injuries and damages to Mrs. Bushway; and caused or contributed to cause the injuries and damages to her. Ethicon failed to use reasonable care to provide adequate warnings to users and handlers of the Ethicon TVT-Obturator and Prolift devices, as discussed herein.

Also, as discussed in my general reports and the report of Dr. Ostergard, Dr. Shobeiri, and Dr. Bruce Rosenzweig, Ethicon failed to include and/or describe the significant adverse events and risks in its IFU for these devices. Ethicon did not fully inform physicians about the numerous adverse reactions/risks associated with these devices despite the fact that Ethicon had scientific knowledge of the risks from the time these products were first sold. As a result, physicians, including Mrs. Bushway's implanting physician were unable to fully consent and inform patients of the risk associated with these products. In addition, some risks included by Ethicon in the IFU were mischaracterized to minimize the actual risk. Finally, when given numerous opportunities to update the IFU, and in the face of specific requests to do so from numerous medical professionals – Ethicon did not make the necessary updates.

To a reasonable degree of medical certainty, this prevented physicians and patients from having the ability to make an informed choice regarding the use of the Ethicon TVT-Obturator and Prolift devices. For a surgeon to properly inform the patient of all the known risks included

in any procedure involving an implantable medical device the surgeon relies upon the manufacturer to have scientific knowledge of and convey all characteristics of its products that could impact safety and efficacy. Specifically, surgeons rely on the "Adverse Events/Risks" section of a medical device IFU to gain scientific knowledge regarding adverse events or undesirable effects that the company knows are associated with the product.

For these reasons, and as fully outlined in my general reports, and those I considered, Ethicon failed to advise Mrs. Bushway's implanting physician of the adverse events and risks associated with the Ethicon TVT-Obturator and Prolift devices. Mrs. Bushway's implanting physician, Dr. Gernt, was not fully able to consent her for the procedure because she was not fully aware of what would happen after these meshes were implanted.

Mrs. Bushway's implanting physician, Dr. Gernt, did not know about many of these risks prior to implanting her with these devices. Ethicon had knowledge of these risks and therefore, it should have included them in the IFU so that Dr. Gernt could perform an appropriate risk-benefit analysis. As a result, to a reasonable degree of medical certainty, it is my opinion Mrs. Bushway was damaged by the injuries she suffered that were not disclosed to her implanting physician by Ethicon.

VI. CONCLUSION

To a reasonable degree of medical certainty, it is my opinion that the Ethicon TVT-Obturator and Prolift devices caused Mrs. Bushway's conditions including continued and worsening urinary incontinence, urinary frequency, urgency, nocturia, vaginal and pelvic pain, urinary tract infections, inflammation, and scar formation, and the need for Interstim implantation. In addition, it is my opinion to a reasonable degree of medical certainty she will experience continued and ongoing complications and need additional medical treatments in the

future related to the permanent complications she suffered from the inadequacies and implantation of the Ethicon TVT-Obturator and Prolift devices. I reserve the right to amend and/or supplement this report if new discovery or facts necessitate amendment or supplementation.

Dated this August 2nd, 2018.

Sincerely,

Konstantin Walmsley, M.D.

EXHIBIT A

Curriculum Vitae

Konstantin Walmsley, Board Certified in Urology, #14764

November 20, 2015

Address: Urology Group of New Jersey
777 Bloomfield Avenue
Glen Ridge, NJ 07028
(973)725-9096

Date and Place of Birth: April 29, 1970; Philadelphia, PA

Marital Status: Married; one daughter, one son

Education:

1988	Diploma, Collegiate High School for Boys, New York, NY
1992	B.A., Honors in Chemistry, University of Pennsylvania, Philadelphia, PA
1997	M.D., Vanderbilt University Medical College, Nashville, TN

Training and Employment:

Spring 1988	Research Assistant, Dept. of Surgical Metabolism, Memorial Sloan-Kettering Cancer Center, New York, NY Sponsor: Nadarajen Vidylingum, PhD
Fall 1989	Research Assistant, Dept. of Neurosurgery, Graduate Hospital, Philadelphia, PA Sponsor: William J. O'Connor, MD
Summer 1993	Research Fellow, Dept. of Physiology, Diabetes Summer Fellowship, Nashville, TN Sponsor: Alan D. Cherrington, PhD
1993-1994	Anatomy and Problem-Based-Learning Tutor Department of Pathology Vanderbilt University, Nashville, TN
1993-1994	MCAT Instructor Stanley H. Kaplan, Nashville, TN
1995-1996	Howard Hughes Medical Institute–NIH Research Scholar, Laboratory of Tumor Immunology and Biology National Cancer Institute, National Institutes of Health, Bethesda, MD Sponsors: Jeffrey Schlom, PhD
1996-1997	Research Assistant, Dept. of Urology Vanderbilt University Medical College Sponsor: Robert J. Matusik, PhD

6/22/97 -6/30/98	Assistant Surgeon New York Presbyterian Hospital-Cornell, New York, NY
7/1/98 -6/30/99	Clinical Associate in Surgery New York Presbyterian Hospital-Cornell, New York, NY
7/1/99 -6/30/03	Clinical Associate in Urology New York Presbyterian Hospital-Cornell and Memorial Sloan-Kettering Cancer Center, New York, NY
7/1/03- 6/30/04	Clinical Instructor in Female Urology and Voiding Dysfunction New York Presbyterian Hospital-Columbia, New York, NY Director of Urodynamics and Department of Urology Helen Hayes Hospital, West Haverstraw, NY
8/15/04- 10/31/08	Associate Urologist and Clinical Instructor Montclair Urological Group, P.A., Glen Ridge, NJ
11/1/08- Present	Partner, Urology Group of New Jersey, Glen Ridge, NJ

Fellowships and Awards:

1988	National Merit Scholarship Semifinalist
1992	Phi Lambda Upsilon Member (Chemistry Honors Society)
1991	Quarterfinalist, Henley Royal Regatta
1992	Silver Medalist, Lightweight Varsity National Rowing Championships
1992	B.A. awarded with honors for senior thesis
1993	Diabetes Research Summer Fellowship
1993-1997	Microbiology and Immunology Honors Society
1994-1997	Candy Robinson Scholarship Society
1995-1996	Howard Hughes Medical Institute - NIH Research Scholar
1997	John L. Shapiro Award for Excellence in Pathology
2002	Honorable Mention, Research Section, Ferdinand C. Valentine Urology Residents Essay Contest, New York, NY
2003-2004	Fellow in Female Urology and Voiding Dysfunction Preceptor: Steven A. Kaplan, MD
2006-present	Top Doctor, NJ Monthly Magazine
2007-present	Top Urologist, Consumers' Research Council of America
2009-2010	Vice President, Medical Staff, Mountainside Hospital, Montclair, NJ
2011-2012	President, Medical Staff, Mountainside Hospital, Montclair, NJ
2012-2014	Chairman, Board of Trustees, Hackensack University Medical Center-Mountainside, Montclair, NJ
2013-present	Chairman, Department of Surgery, Hackensack University Medical Center-Mountainside, Montclair, NJ
2013-present	Chairman, Credentialing Committee, Hackensack University Medical Center-Mountainside, Montclair, NJ

Activities:

1979-1984	Metropolitan Opera, Boy Soprano
1989-1992	Men's Varsity Lightweight Crew, University of Pennsylvania
1993-1995	Alcohol and Substance Abuse Program Big Brother, Nashville, TN
1997-2003	Cornell Urology Urinary Track Team, 13 marathons completed (personal record 3:04:59)
2012-2016	Completed five ultramarathons

Abstracts and Presentations:

1. "The Conducting and Thermal Properties of Polyaniline Salts" Walmsley K. Honors Program, Chemistry, University of Pennsylvania, Philadelphia, PA, May 3, 1992

2. "The Vanderbilt Transplant Center: Results Between 1998 and 1993" Pinson CW, Walmsley K, Richie RE, Johnson JE, Frist W, Wolff SW. Poster presentation at the *American College of Surgeons*, San Francisco, CA, Oct. 12-14, 1993.

3. "Evidence that the Brain is Directly Sensitive to Physiologic Levels of Plasma Insulin in Vivo" Walmsley K, Dunham BP, Davis SD, Shavers C, Snead WP, Hastings JR, Cherrington AD. Poster Presentation at the *American Diabetes Association* Annual Meeting, New Orleans, LA, June 11-14, 1994.

4. "Vago-Sympathetic Blockade Decreases Basal Hepatic Glucose Production in the Conscious Dog" Walmsley K, Neal DW, Hastings JR, Cherrington AD. Poster presentation at the *American Diabetes Association* Annual Meeting, Atlanta, GA, June 10-13, 1995.

5. "Generation of Human T-Cell Lines Specific for Prostate Specific Antigen Using an Oligo-Epitope Peptide" Walmsley K, Correale P, Nieroda CN, Zaremba S, Tsang, KY, Schlom J. Podium presentation at the *Proceedings of the American Association of Cancer Research,* Washington, D.C., April 22-25, 1996 and *Class of 1995-1996 Scientific Presentations,* Howard Hughes Medical Institute-National Institutes of Health Research Scholars Program, Bethesda, MD, May 22, 1996.

6. "CEA-Specific Cytotoxic T Cell Immunity in Phase I Clinical Trials Using a Recombinant CEA-Vaccinia Vaccine" Tsang KY, Zhu MZ, Nieroda CN, Correale P, Zaremba S, Walmsley K, Schmitz, J, Hamilton, J. Podium presentation at the *Proceedings of the American Association of Cancer Research*, Washington, D.C., April 22-25, 1996.

7. "The Inheritance of Varicoceles" Walmsley K, Goldstein M. Poster presentation at the Annual Meeting of the *American Urologic Association,* Anaheim, CA, June 12-16, 2001. (an AUA CD-ROM top poster presentation).

8. "Varicocele Management in the Pediatric Patient: Results with Microsurgical Varicicocelectomy" Walmsley K, Coleman J, Kelly C, Goldstein M, Poppas DP. Podium presentation at the Annual Meeting of *American Academy of Pediatrics*, San Francisco, CA, October 16-20, 2001.

9. "Effects of Antibody to Transforming Growth Factor Beta in Unilateral Ureteral Obstruction of Mice Lacking the Gene for Inducible Nitric Oxide Synthase" Walmsley K, Seshun SV, Chen J, Ledbetter S, Vaughan ED, Poppas DP, Felsen D. *Ferdinand C. Valentine Urology Residents Essay Meeting*, New York, NY, March 20, 2002. Poster presentation at the Annual Meeting of the *American Urological Association*, Orlando, FL, May 25-30, 2002 (an AUA CD-ROM top poster presentation.

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13. "The Diagnosis and Management of BPH." Grand Rounds, Mountainside Hospital, March 8, 2005.

14. "Overactive Bladder and Urinary Incontinence-Treatment Options in the 21st Century." Grand Rounds, Mountainside Hospital, February 6, 2006.

15. "PSA Screening in the 21st Century: The New State of the Art." Grand Rounds, Mountainside Hospital, September 8, 2007.

16. "Updates in the Diagnosis and Treatment of Prostate Enlargement." Grand Rounds, Mountainside Hospital, March 11, 2010.

17. "Hypogonadism: Prevalence, Diagnosis, and Treatment Options." Grand Rounds, Hackensack University Medical Center, April 4, 2013.

Publications:

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2. Davis SN, Dunham B, Walmsley K, Shavers C, Neal D, Williams P, Cherrington AD. Brain of the conscious dog is sensitive to to physiological changes in circulating insulin *Am J Physiol* **272(4 Pt 1):** E567-575

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4. Walmsley K, Te AE. Localized prostate blocks in minimally invasive procedures, *Urologix* 2003, **(3):** 4-6.

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8. Walmsley K, Gjertsen CK, Kaplan SA. Medical management of BPH- An update. Manuscript pending for *AUA Update Series*.

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11. Kaplan SA, Walmsley K, and Te AE. Tolterodine extended release attenuates lower urinary tract symptoms in men with benign prostatic hyperplasia. J Urol 2005 Nov; 174(6): 2273-5.

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EXHIBIT B

Prior Testimonies

2007 – Mucchiolo vs Steckel et al: (Case in which I was a resident assisting on case with subsequent complications)

2010 – Gonzalez v. Ethicon (case of Ethicon stapler resulting in complications)

2011 – Case in long island involving delay in diagnosis of BPH in patient with urinary retention

2012: Henebury vs. Corea (case of a complication following ureteroscopy)

2013: Schubert vs. Roberts (Prolift complication)

2013 Sorezza vs. Scheuch (case of a complication following PCNL)

3/2014 – Martinez vs. AMS

5/2014 – Humphreys vs Crothall Heath Care (case of possible sexual harassment)

7/2014 – Betancourt vs. BSC

7/2014 – Nunez vs. BSC

11/2014 – Ash vs. Bard; Earls vs. Bard

12/2014 - Curtis vs. BSC; Varnadoe vs. BSC; Curtis vs. BSC; Davis vs BSC

11/2015 – Stewart vs. Meshesha

2/2016 – Del Castillo vs. Caso

3/2016 – Ridgley vs. Ethicon; Fox vs. Ethicon

6/2016: Lindberg vs. Ethicon

6/2016: Manor vs. Ethicon; Martin vs. Ethicon; Pridmore vs. Ethicon; Bailey vs. Ethicon

6/2016: Vanbuskirk vs. Ethicon; Barr vs. Ethicon; Javins vs. Ethicon; Garcia vs. Ethicon

7/2016: Birt vs. Shashoua

8/2016: Birt vs. Ethicon; Baker vs. Ethicon; Ward vs. Ethicon; Phillips vs. Ethicon

10/16: Mattingly vs. Ethicon; Berry vs. Ethicon

11/16: Collins vs. Bard

2/17: Ray vs. Ethicon

COMPENSATION FOR MY REVIEW, STUDY, AND TESTIMONY

My fee for review of medical records, corporate documents and other related materials, testimony, and travel time is an hourly rate of $500.00 per hour.

EXHIBIT C

Case Specific Reliance List
Rose Marie Bushway
Dr. Konstantin Walmsley, M.D.

Medical Reviewed:

- Cookville Regional Medical Center
- Dr. Bert E. Geer

Litigation Documents Reviewed:

- Short Form File Stamped Complaint
- Plaintiff Profile Form
- Plaintiff Fact Sheet

Materials Reviewed

Depositions of Medical Providers
Depositions of Client and Partner (if applicable)
Expert Reports Related to Case
Medical & Billing Records
Instructions for Use

Boston Scientific Corp.'s TVM products Instructions for Use
Boston Scientific Corp.'s TVM products Patient Brochures

Incorporated Materials

All materials cited in and reviewed for the TVT general causation reports

Medical Literature

AMA 8.08

Boston Scientific Corp.'s TVM products Instructions for Use

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